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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/829,243

04/22/2004

Nobuhiko Yui

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WASHINGTON, DC 20006-1021

EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

09/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/829,243	Applicant(s) YUI ET AL.	
	Examiner BLESSING M. FUBARA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 23-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 06/09/08. Claims 1-20 are amended. New claims 23-30 are added. Claims 1-30 are pending.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-20 and new claims 23-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejections.

3. While original claims 1 and 2 require the moisture content to not exceed 98 wt. %, and while paragraph 29 disclose that the saturated moisture content: to not exceed "98 wt. %, and preferably not exceeding 96 wt. %, more preferably not exceeding 93 wt. %, further preferably not exceeding 89 wt. %. The lowest limit of the saturated moisture content is not specified, however, is preferably not less than 50 wt. %, more preferably not less than 60 wt. %, further preferably not less than 70 wt. %, particularly preferably not less than 80 wt. %," the

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specification as originally filed does not envision the moisture ranges now recited in the amended claims.

4. Applicant may overcome the rejection by removing what was not originally envisioned, the new matter, from the claims.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 2 and 7-13 remain rejected and new claims 23-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Yasuhisa (JP 5-229934, computer translation) for reasons of record and reiterated herein below with a minor modification to address the amendment to claims 1 and 2 and inclusion of new claim 23-30

7. Yasuhisa discloses drug deliver composition that comprises cross-linked polysaccharide gel such as hyaluronic acid and the cross-linking agent is polyfunctional glycidyl ether (para. [0009]-[0012], meeting the limitations polysaccharide gel and cross-linking agents of the claims. Claims 11 and 12 are product by process claims. The recitation of “wherein the degradable gel decomposes and dissipates ... or pest control” in claims 1 and 2 addresses the properties of the composition and since a composition and its properties cannot be separated, the composition of

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the prior art would inherently display those properties being capable of exhibiting the properties. For claims 23-28, it is noted that the JP reference teaches water content of from 50 to 99.8% (last 2 lines of paragraph 0010 of the translation) such that points within the disclosed range touches points within the recited range.

8. Claims 1-6, 11, 12 and 17-20 remain rejected and new claims 23-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Igarashi (US 4,997,653) for reasons of record and reiterated herein below with a minor modification to address the amendment to claims 1 and 2.

Igarashi discloses a topical preparation comprising danazol (abstract; column 2, lines 26, 38; column 4, line 1, Example 1) meeting claims 3-6, polysorbate (Example 1; column 4, lines 12) meeting claims 17-20, matrix polymer in the presence of cross-linking agent (column 3, lines 55-67; column 4, lines 4-9) meeting the biodegradable polymer of claims 1 and 2. Claims 11 and 12 are product by process claims and thus Igarashi's product meets the claims. Igarashi uses the device to treat endometriosis (title; abstract; column 2, line 27; column 4, lines 64-68; column 7, lines 3-44). The recitation of "wherein the degradable gel decomposes and dissipates ... or pest control" in claims 1 and 2 addresses the properties of the composition and since a composition and its properties cannot be separated, the composition of the prior art would inherently display those properties being capable of exhibiting the properties.

9. Claims 1-16 remain rejected and new claims 23-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Yui et al. (US 2002/0150605) for reasons of record and reiterated herein below with a minor modification to address the amendment to claims 1 and 2 and the inclusion of new claims 23-30..

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Yui discloses composition that contains danazole (para. [0029], [0037], [0064], [0068], [0069], [0077], [0078] and [0083], meeting the requirements of claims 3-6; ethyleneglycol diglycidyl ether cross-lined polysaccharide that is hyaluronic acid (abstract; para. [0053], [0007], [0030]; [0033], [0035], [0036]) meeting claims 7-10, and 13-16 and new claims 29 and 30. Claims 11 and 12 are product by process claims and the device is used in endometriosis (abstract, para. [0001], [0006], [0008], [0011], [0017], [0028], [0032], [0053], [0054], [0056], [0064], [0067]-[0070]. The recitation of “wherein the degradable gel decomposes and dissipates ... or pest control” in claims 1 and 2 addresses the properties of the composition and since a composition and its properties cannot be separated, the composition of the prior art would inherently display those properties being capable of exhibiting the properties.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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12. Claims 1-20 remain rejected and new claims 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Igarashi (4,977,653) and Yui (2002/0150605) for reasons of record and reiterated herein below with a minor modification to including new claims 29 and 30.

Both references are described above. Both references are used for treating endometriosis as stated above. Igarashi and Yui each teach the composition. Igarashi fails to teach a polysaccharide polymer of claims 7-10, 29 and 30. Yui fails to teach a surfactant of claims 17-20. The individual compositions are used to treat endometriosis. However, "it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, taking the teachings of Yui and Igarashi, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that the combined compositions of Yui and Igarashi would be effective in the treatment of endometriosis.

Response to Arguments

13. Applicant's arguments filed 6/09/08 have been fully considered but they are not persuasive.

14. Applicant presented combined argument against the rejections. In so doing, applicant argues that the examiner had not addressed the saturated moisture content of the degradable gel and that the amendment to the claims reciting a water/moisture content of from not less than 50 wt% to not exceeding 98 weight % distinguishes the claims over the composition of the prior art and specifically, Igarashi and it relates to new claims 29 and 30. The examiner disagrees that

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the prior art may not teach the water content of the gel. Firstly, the water content of the gel is a property of the gel and specifically in claims 1 and 2 claiming generic degradable gel that reads on the degradable gel of the prior art. Claims 29 and 30 that recite polysaccharide as the compound of the, it is noted that claims 29 and 30 are not included in the rejections over Igarashi alone. Secondly, while the water content of the gel is a property of the gel, it is noted that Yasuhisa discloses a water content of from 50 to 99.8% (last 2 lines of paragraph 0010 of the translation) such that points within the disclosed range touches points within the recited range. 50% is less than 60% wt (lower limit of claims 23, 24), less than 70 wt% (lower limit of claims 25, 26) and less than 80 wt% (lower limit of claims 27 and 28) and points within Yasuhisa's range touches points within the recited range.

No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/
Examiner, Art Unit 1618